

Fiscal Note for addition to rule for North Carolina Division of Public Health Requires OSBM Review

Agency: Dept. Of Health and Human Services, Division of Public Health, Epidemiology Section, Communicable Disease Branch

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Rule Citations: 10A NCAC 41A .0101 (Reportable Diseases and Conditions)

Purpose of Addition: Require laboratories that utilize electronic laboratory reporting to report directly to the NC Division of Public Health HIV genotypic laboratory test results.

Relevant Statutes: GS 130A-134; 130A-139; 130A-141

State Agency Impact: Yes
Local Agency Impact: No
Private-Sector Impact: Yes (minimal opportunity costs)
Substantial Economic Impact: No
Significant Rule Change: Yes

Reason for Proposed Amendment

North Carolina Communicable Disease Branch

The core mission of the Communicable Disease Branch (CDB) of the North Carolina (NC) Division of Public Health Epidemiology Section is to identify, prevent, and control communicable diseases to protect the public's health. As part of this mission, the Branch conducts surveillance for communicable diseases, including HIV, other sexually transmitted diseases (STDs), and other diseases reportable under NC law. Branch staff review case report data and provide consultation and assistance to local health departments (LHDs) and others to investigate disease cases and outbreaks, determine appropriate control measures to mitigate disease transmission, and ensure that control measures are applied. Disease surveillance data are used to identify affected populations and potential public health interventions, allocate resources, and evaluate public health programs.

Electronic Laboratory Reporting

Electronic Laboratory Reporting (ELR) is the electronic transmission from laboratories to public health of laboratory reports which identify reportable conditions. ELR improves the timeliness, accuracy, and completeness of data reported for surveillance. A total of 5 healthcare facility and commercial laboratories currently utilize ELR to transmit laboratory reports for reportable conditions to the NC Division of Public Health.

HIV Genotypic Testing

According to core performance measures set forth by the U.S. Department of Health and Human Services' HIV/AIDS Bureau, HIV care providers should obtain each patient's HIV drug resistance profile before the initiation of HIV therapy. The preferred resistance testing used to guide antiretroviral (ARV) therapy is HIV genotypic testing in which regions coding for drug resistance in the HIV genome are sequenced. Therefore, HIV care providers adhering to best practice guidelines routinely order this laboratory test. It is estimated that sequencing is performed 600-1,200 times per year in North Carolina. Although HIV infection is reportable by law in the state, there is no legal requirement to report HIV genotypic data to public health authorities in NC.

Molecular HIV surveillance includes the collection of HIV genotypic data to assess trends in acquired and transmitted HIV drug resistance, evaluate HIV genetic diversity, and describe HIV transmission patterns. Using existing systems, this HIV genotypic data can be merged with the HIV demographic and transmission risk information already being collected for public health surveillance in NC. The resulting database would facilitate development of HIV molecular epidemiologic profiles for NC and evaluation of HIV prevention and treatment strategies across the state. In addition to

assessments of care, these data can be used to describe genetic networks. These networks can then be used to prioritize patient and partner services for patients in networks with recent transmission, allowing North Carolina to identify people living with HIV who are either not yet diagnosed or not in medical care and receiving suppressive treatment.

An amendment to the NC Reportable Diseases and Conditions rule is needed to require laboratories that perform HIV genotypic testing and utilize ELR to report HIV genotypic laboratory test results directly to the NC Division of Public Health.

Opportunity Cost

Reporting of HIV genotype in North Carolina

State Agency Impact

The proposed amendment will have a fiscal impact on the State Agency. The NC Division of Public Health Information Technology team will update the North Carolina Electronic Disease Surveillance System (NC EDSS) at one-time cost of \$13,597 (Table 1). This update will include development and implementation of the case processor, allowing NC EDSS to receive positive HIV laboratory test results via ELR. This amendment will impose an annual cost, based on the employee cost (salary plus benefits) of a registrar monitoring laboratory test results and working with reporting laboratories (0.5 FTE) and the employee cost of an analyst using genotype data to define HIV clusters in North Carolina (0.5 FTE) of \$67,649 (Table 1)).

Local Agency Impact

The proposed amendment has no fiscal impact on LHDs. LHD communicable disease staff are not required to conduct epidemiologic investigations on HIV cases. All HIV case data will be managed by the CDB.

Private-Sector Impact

The proposed amendment will have no fiscal impact on the private sector. Laboratories are not mandated to initiate ELR with this amendment. However, upon initiating ELR to transmit reportable disease test results to public health, laboratories must meet this reporting requirement. No unique actions are required for reporting HIV genotype results via ELR. Therefore, the requirement to transmit HIV genotype results poses no additional burden on laboratories. With this amendment, reporting requirements remain unchanged for physicians, other healthcare providers, and healthcare facilities, with the exception of healthcare facility laboratories that utilize ELR.

Table 1. Resources and impacts associated with the reporting of all positive laboratory test results used to diagnosis hepatitis C virus infection in North Carolina

Resources	Impact
A. Impact on State Agency	
Upgrades to NC EDSS* to receive HCV case reports	\$13,597 (one-time cost)
Maintenance cost	\$67,649 per year (annual cost)
Total one-time cost to State Agency	\$13,597
Total annual cost to State Agency	\$67,649
B. Impact on Local Agencies	
None	\$0
C. Impact on Private Sector	
Data to allow earlier diagnosis of HIV, better targeted prevention and treatment strategies	Unquantified annual benefit
Total Impact	
Total one-time cost	\$13,597
Total annual cost	\$67,649
Total annual benefits	Unquantified

*North Carolina Electronic Disease Surveillance System

10A NCAC 41a .0101 is proposed for amendment as follows:

10A ncac 41a .0101 REPORTABLE DISEASES AND CONDITIONS

(a) The following named diseases and conditions are declared to be dangerous to the public health and are hereby made reportable within the time period specified after the disease or condition is reasonably suspected to exist:

- (1) acquired immune deficiency syndrome (AIDS) - 24 hours;
- (2) anthrax - immediately;
- (3) botulism - immediately;
- (4) brucellosis - 7 days;
- (5) campylobacter infection - 24 hours;
- (6) chancroid - 24 hours;
- (7) chikungunya virus infection - 24 hours;
- (8) chlamydial infection (laboratory confirmed) - 7 days;
- (9) cholera - 24 hours;
- (10) Creutzfeldt-Jakob disease – 7 days;
- (11) cryptosporidiosis – 24 hours;
- (12) cyclosporiasis – 24 hours;
- (13) dengue - 7 days;
- (14) diphtheria - 24 hours;
- (15) Escherichia coli, shiga toxin-producing - 24 hours;
- (16) ehrlichiosis – 7 days;
- (17) encephalitis, arboviral - 7 days;
- (18) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other and unknown causes - 24 hours;
- (19) gonorrhea - 24 hours;
- (20) granuloma inguinale - 24 hours;
- (21) Haemophilus influenzae, invasive disease - 24 hours;
- (22) Hantavirus infection – 7 days;
- (23) Hemolytic-uremic syndrome – 24 hours;
- (24) Hemorrhagic fever virus infection – immediately;
- (25) hepatitis A - 24 hours;
- (26) hepatitis B - 24 hours;
- (27) hepatitis B carriage - 7 days;
- (28) hepatitis C, acute – 7 days;
- (29) human immunodeficiency virus (HIV) infection confirmed - 24 hours;
- (30) influenza virus infection causing death – 24 hours;
- (31) legionellosis - 7 days;
- (32) leprosy – 7 days;
- (33) leptospirosis - 7 days;
- (34) listeriosis – 24 hours;
- (35) Lyme disease - 7 days;
- (36) Lymphogranuloma venereum - 7 days;
- (37) malaria - 7 days;
- (38) measles (rubeola) - 24 hours;
- (39) meningitis, pneumococcal - 7 days;
- (40) meningococcal disease - 24 hours;
- (41) Middle East respiratory syndrome (MERS) - 24 hours;
- (42) monkeypox – 24 hours;
- (43) mumps - 7 days;
- (44) nongonococcal urethritis - 7 days;
- (45) novel influenza virus infection – immediately;
- (46) plague - immediately;

- (47) paralytic poliomyelitis - 24 hours;
- (48) pelvic inflammatory disease – 7 days;
- (49) psittacosis - 7 days;
- (50) Q fever - 7 days;
- (51) rabies, human - 24 hours;
- (52) Rocky Mountain spotted fever - 7 days;
- (53) rubella - 24 hours;
- (54) rubella congenital syndrome - 7 days;
- (55) salmonellosis - 24 hours;
- (56) severe acute respiratory syndrome (SARS) – 24 hours;
- (57) shigellosis - 24 hours;
- (58) smallpox - immediately;
- (59) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
- (60) streptococcal infection, Group A, invasive disease - 7 days;
- (61) syphilis - 24 hours;
- (62) tetanus - 7 days;
- (63) toxic shock syndrome - 7 days;
- (64) trichinosis - 7 days;
- (65) tuberculosis - 24 hours;
- (66) tularemia – immediately;
- (66) typhoid - 24 hours;
- (67) typhoid carriage (Salmonella typhi) - 7 days;
- (68) typhus, epidemic (louse-borne) - 7 days;
- (69) vaccinia – 24 hours;
- (70) vibrio infection (other than cholera) – 24 hours;
- (71) whooping cough – 24 hours; and
- (72) yellow fever - 7 days.

(b) For purposes of reporting, "confirmed human immunodeficiency virus (HIV) infection" is defined as a positive virus culture, repeatedly reactive EIA antibody test confirmed by western blot or indirect immunofluorescent antibody test, positive nucleic acid detection (NAT) test, or other confirmed testing method approved by the Director of the State Public Health Laboratory conducted on or after February 1, 1990. In selecting additional tests for approval, the Director of the State Public Health Laboratory shall consider whether such tests have been approved by the federal Food and Drug Administration, recommended by the federal Centers for Disease Control and Prevention, and endorsed by the Association of Public Health Laboratories.

(c) In addition to the laboratory reports for Mycobacterium tuberculosis, Neisseria gonorrhoeae, and syphilis specified in G.S. 130A-139, laboratories shall report:

- (1) Isolation or other specific identification of the following organisms or their products from human clinical specimens:
 - (A) Any hantavirus or hemorrhagic fever virus.
 - (B) Arthropod-borne virus (any type).
 - (C) Bacillus anthracis, the cause of anthrax.
 - (D) Bordetella pertussis, the cause of whooping cough (pertussis).
 - (E) Borrelia burgdorferi, the cause of Lyme disease (confirmed tests).
 - (F) Brucella spp., the causes of brucellosis.
 - (G) Campylobacter spp., the causes of campylobacteriosis.
 - (H) Chlamydia trachomatis, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.
 - (I) Clostridium botulinum, a cause of botulism.
 - (J) Clostridium tetani, the cause of tetanus.
 - (K) Corynebacterium diphtheriae, the cause of diphtheria.
 - (L) Coxiella burnetii, the cause of Q fever.
 - (M) Cryptosporidium parvum, the cause of human cryptosporidiosis.
 - (N) Cyclospora cayentanesis, the cause of cyclosporiasis.
 - (O) Ehrlichia spp., the causes of ehrlichiosis.

- (P) Shiga toxin-producing *Escherichia coli*, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.
- (Q) *Francisella tularensis*, the cause of tularemia.
- (R) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
- (S) Human Immunodeficiency Virus, the cause of AIDS.
- (T) *Legionella* spp., the causes of legionellosis.
- (U) *Leptospira* spp., the causes of leptospirosis.
- (V) *Listeria monocytogenes*, the cause of listeriosis.
- (W) Middle East respiratory syndrome virus.
- (X) Monkeypox.
- (Y) *Mycobacterium leprae*, the cause of leprosy.
- (Z) *Plasmodium falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*, the causes of malaria in humans.
- (AA) Poliovirus (any), the cause of poliomyelitis.
- (BB) Rabies virus.
- (CC) *Rickettsia rickettsii*, the cause of Rocky Mountain spotted fever.
- (DD) Rubella virus.
- (EE) *Salmonella* spp., the causes of salmonellosis.
- (FF) *Shigella* spp., the causes of shigellosis.
- (GG) Smallpox virus, the cause of smallpox.
- (HH) *Staphylococcus aureus* with reduced susceptibility to vanomycin.
- (II) *Trichinella spiralis*, the cause of trichinosis.
- (JJ) Vaccinia virus.
- (KK) *Vibrio* spp., the causes of cholera and other vibrioses.
- (LL) Yellow fever virus.
- (MM) *Yersinia pestis*, the cause of plague.

(2) Isolation or other specific identification of the following organisms from normally sterile human body sites:

- (A) Group A *Streptococcus pyogenes* (group A streptococci).
- (B) *Haemophilus influenzae*, serotype b.
- (C) *Neisseria meningitidis*, the cause of meningococcal disease.

(3) Positive serologic test results, as specified, for the following infections:

- (A) Fourfold or greater changes or equivalent changes in serum antibody titers to:
 - (i) Any arthropod-borne viruses associated with meningitis or encephalitis in a human.
 - (ii) Any hantavirus or hemorrhagic fever virus.
 - (iii) *Chlamydia psittaci*, the cause of psittacosis.
 - (iv) *Coxiella burnetii*, the cause of Q fever.
 - (v) Dengue virus.
 - (vi) *Ehrlichia* spp., the causes of ehrlichiosis.
 - (vii) Measles (rubeola) virus.
 - (viii) Mumps virus.
 - (ix) *Rickettsia rickettsii*, the cause of Rocky Mountain spotted fever.
 - (x) Rubella virus.
 - (xi) Yellow fever virus.
- (B) The presence of IgM serum antibodies to:
 - (i) *Chlamydia psittaci*.
 - (ii) Hepatitis A virus.
 - (iii) Hepatitis B virus core antigen.
 - (iv) Rubella virus.
 - (v) Rubeola (measles) virus.
 - (vi) Yellow fever virus.

(4) Laboratory results from tests to determine the absolute and relative counts for the T-helper (CD4) subset of lymphocytes and all results from tests to determine HIV viral load.

(d) Laboratories utilizing electronic laboratory reporting (ELR) shall report:

- (1) All positive laboratory results from tests used to diagnosis chronic hepatitis C infection, including:
 - (A) Antibodies to hepatitis C virus tests (including the test specific signal to cut-off (s/c) ratio)
 - (B) Nucleic acid test for hepatitis C virus

(C) Hepatitis C antigen(s) tests

(D) Hepatitis C genotypic tests

(2) All HIV genotypic test results, including when available:

(A) The entire nucleotide sequence and/or

(B) The pol region sequence (including all regions protease (PR)/reverse transcriptase (RT) and integrase inhibitor (INI) genes).

History Note: Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141